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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/817,172

04/02/2004

Donald P. Bushby

Plantar Fasciitis

3082

7590
Donald P. Bushby
1211 Nagle Street
Houston, TX 77003

04/16/2008

EXAMINER

PATEL, TARLA R

ART UNIT

PAPER NUMBER

3772

MAIL DATE

DELIVERY MODE

04/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/817,172 | Applicant(s) BUSHBY, DONALD P. | |
| | Examiner TARLA R. PATEL | Art Unit 3772 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 44-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 44-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 56 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 56 recites the limitation "strap and tab adhered to the outer skin surface of the foot provides additional resistance to lateral and longitudinal forces" in claim is not supported by the originally filed specification. In originally filed specification on page 15 in paragraph 0044 applicant discloses only front straps 450 near the ball of the foot provides extra resistance to lateral and longitudinal forces.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 44 and 56 recites the limitation "**the** outer skin", "**the** sole", "**the** plantar fascia", "**the** region", "**the** heel" and "**the** distal end of the toes" in claim is not clear and there are lack of antecedent basis of claimed " **the** outer skin", "**the** sole", "**the** plantar fascia", "**the** region", "the heel" and "the distal end of the toes" in claim and must be replaced with "an outer skin", "a sole", "a plantar fascia", "a region", "a heel" and "a distal end of the toes" to be presented properly

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claim limitations. There is insufficient antecedent basis for this limitation in the claim.

5. Claims 44 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims 44 and 56 recite limitation "sole engaging surface, and said stretch-resistant sole member" implies two structure, however, first paragraph defining the sole engaging surface as part of sole member. The claimed limitation "sole engaging surface, and said stretch-resistant sole member" seems to be two distinct structure element of the foot support. An appropriate action is needed.

6. Claim 56 recites the limitation "strap and tab adhered to the outer skin surface of the foot provides additional resistance to lateral and longitudinal forces" in claim is not supported by the originally filed specification. In originally filed specification on page 15 in paragraph 0044 applicant discloses only front straps 450 near the ball of the foot provides extra resistance to lateral and longitudinal forces. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 53 recites the limitation "said arch strap" recited in line 5 of the claim is not supported by the independent claim from which the claim 53 depends. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 44, 56, 62 and 66 are rejected under 35 U.S.C. 102(e) as being anticipated by Burgess (6,640,465).

Burgess discloses an orthotic plantar fascia device for providing support to and reducing stress on, the plantar fascia of a human foot. The device comprises a thin flexible stretch-resistant device (110) (as best can be understood from applicant's specification and claims the "stretch-resistant device" is a sufficiently flexible article with adhesive lining and there in no other distinguish structures is required therefore, the device of Burgess meets this claimed limitation), and the device has a sole engaging surface (see figure 2), sized and shaped to engage the outer skin tissue on the sole of the foot (column 2 lines 38-40) and extend along the plantar fascia region of the foot from about the ball of the foot to the heel of the foot for providing support to the plantar fascia region of the foot (see fig 2). The device further includes an adhesive layer (120) on the sole engaging surface for adhering the device directly to the outer skin tissue on the sole of the foot (column 2 lines 62-67) and a protective cover (150) removably disposed over adhesive layer, that when removed, exposes the adhesive layer (column 4 lines 50-55). The stretch-resistant device, as best can be understood from applicant's specification and claims, the device of Burgess described above, is inherently stretch-resistant to restrict extension and stretching of the outer skin tissue on the sole of the foot, when the device of Burgess adhered to the sole, such that tension forces applied to the plantar fascia from the forces on an arch of the foot which push the bones of the foot downwardly are shared with a the device to restrict stretching (when the device described above adheres to the bottom of the foot or sole) and are reduce tension in the plantar fascia.

With respect to limitations of Burgess inherently discloses the method for reducing stress on the plantar fascia of a human foot comprising the steps of providing a thin flexible device of uniform

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thickness having sole engaging surface and adhering sole engaging surface to the outer skin tissue on the sole of the foot to extend from the heel of the foot to at least the mid portion of the foot to provide support to the plantar fascia region, since Burgess discloses the structure limitation of the device and as best can be understood from applicant's specification and claims the "stretch-resistant device" is a sufficiently flexible article with adhesive lining and there in no other distinguish structures is required.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 48-54 and 57-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess (465).

Burgess substantially disclose the invention as claimed; see rejection to claims 44, 56, 62, and 66 above, further, Burgess discloses a device that has a uniform thickness (column 3 lines 52-54) of less than about 30 mils, (since column 3 lines 13-15, describes the thickness of about 1 mm to about 5 mm inherently discloses the less than about 30 mils required by claim, since examiner interprets "about" language as broadest reasonable interpretation, since 1 mils= 0.0254 mm) and formed of a fabric material (column 4 lines 5-10). However, Burgess does not discloses that device is 30 mils (0.762 mm) in thickness. At the time of the invention was made, it would have been obvious design choice to one having ordinary skill in the art to have thickness of 30 mils, since, such a modification would have involved a mere change in the size

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of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

12. Claims 48-54, and 57-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess (465) in view of Turtzo (2002/0188239).

Burgess discloses an orthotic plantar fascia device for providing support to and reducing stress on, the plantar fascia of a human foot. The device comprises a thin flexible stretch-resistant device (110) (as best can be understood from applicant's specification and claims the "stretch-resistant device" is a sufficiently flexible article with adhesive lining and there in no other distinguish structures is required therefore, the device of Burgess meets this claimed limitation), and the device has a sole engaging surface (see figure 2), sized and shaped to engage the outer skin tissue on the sole of the foot (column 2 lines 38-40) and extend along the plantar fascia region of the foot from about the ball of the foot to the heel of the foot for providing support to the plantar fascia region of the foot (see fig 2). The device further includes an adhesive layer (120) on the sole engaging surface for adhering the device directly to the outer skin tissue on the sole of the foot (column 2 lines 62-67) and a protective cover (150) removably disposed over adhesive layer, that when removed, exposes the adhesive layer (column 4 lines 50-55). The stretch-resistant device, as best can be understood from applicant's specification and claims, the device of Burgess described above, is inherently stretch-resistant to restrict extension and stretching of the outer skin tissue on the sole of the foot, when the device of Burgess adhered to the sole, such that tension forces applied to the plantar fascia from the forces on an arch of the foot which push the bones of the foot downwardly are shared with a the device to restrict stretching (when the device described above adheres to the bottom of the foot or sole) and are reduce tension in the plantar fascia.

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However, Burgess does not disclose thin flexible straps extending laterally outward from opposite sides to at least partially encircle the talus, the navicular, the cuneiform and the cuboid region of the foot, an arch strap and a heel strap, wherein the straps can be adhered to the foot by an adhesive for securing the straps around the portions of the foot as required by claims 48,51,53,56,57,58,59,60, and 61 and With respect to claims 50,52 and 54, further, Burgess does not disclose the straps are integrally formed with device (see fig 1).

However, Turtzo teaches a foot splint for treatment of plantar fasciitis comprising thin flexible straps extending laterally outward from opposite sides to at least partially encircle the talus, the navicular, the cuneiform and the cuboid region of the foot, an arch strap and a heel strap (see figs 4, 14,15,42,44), wherein the straps can be adhered to the foot by an adhesive [see paragraph 0026,0030] for securing the straps around the portions of the foot [0030] as required by claims 48,51,53,56,57,58,59,60, and 61 and further, Turtzo discloses the straps are integrally formed with device (see fig 1) as required by claims 50,52 and 54. At the time of the invention, it would have been an obvious to one skilled in art to have to make the device of Burgess to have straps having adhesive, as taught by of Turtzo to adding adhesive to the top surface of the device to have adhesive on top surface of the device to adhere the support device to the bottom of the foot and to secure the device better to sole of the foot.

13. With respect to claims 44,56, and 60, the limitations of “restricting extension and stretching of the outer skin tissue on the sole of the foot”, when the device described above adheres to sole, such that the tension forces applied to the plantar fascia from the forces on an arch of the foot which push the bones of the foot downwardly are shared with device to restrict stretching (when the device described above adheres to the bottom of the feet or sole) and are able to reduce tension in the plantar fascia (0027), the examiner interprets the limitations of securing the device on user’s foot Burgess and Turzto device result in treating pain in at least

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one of the heel, or arch or ball of the foot (see paragraph 0016 and 0027) and controls the step to prevent extension and stretching, reduce tension on the plantar fascia of the foot.

14. Claims 47, 67 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess in view of Huddleston et al. (4,997,709).

Burgess substantially disclose the invention as claimed; see rejection to claims 44, 56, 62, and 66 above; Burgess does not disclose a support device that has less than 15% elongation when subjected to a tensile load (lb/in-width) approximately equivalent to 25 pounds/inch in accordance with ASTM D3759.

However, Huddleston et al. teaches novel adhesives and tapes having the tensile load (lb/in-width) approximately equivalent to 25 pounds/inch in accordance with ASTM D3759 (column 1 lines 48-63). At the time of the invention, it would have been an obvious to one skilled in art to use the tapes/adhesives of the tensile load (lb/in-width) approximately equivalent to 25 pounds/inch in accordance with ASTM D3759 to the device of Burgess, as taught by Huddleston et al. to have more resiliencies to the device.

15. Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess in view of Dalton (2004/0118017).

Burgess substantially disclose the invention as claimed; see rejection to claims 44, 56, 62, and 66 above; Burgess does not disclose a support device that has a sole includes medicinal additives, anti-fungal treatments, anti-microbial treatments, anti-inflammatory treatments, deodorants, and tea tree oil.

However, Dalton teaches a support device having an insole that is treated with antibacterial agent (0031). At the time of the invention, it would have been an obvious to one skilled in art to

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treat the sole of the support device of Burgess with antibacterial agent to avoid odor causing bacteria and fungus.

16. Claims 63, 64, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burgess in view of Turtzo.

Burgess substantially disclose the invention as claimed; see rejection to claims 44, 56, 62, and 66 above; Burgess does not disclose a support device that includes thin flexible straps extending laterally outward from opposite sides to at least partially encircle the talus, the navicular, the cuneiform and the cuboid region of the foot, an arch strap and a heel strap, wherein straps can be adhered to the foot by an adhesive for securing around the portions of the foot.

However, Turtzo teaches a support device including thin flexible straps extending laterally outward from opposite sides to at least partially encircle the talus, the navicular, the cuneiform and the cuboid region of the foot, arch strap and heel strap (see fig 4, elements 14, 15, 42, 44), wherein straps can be adhered to the foot by an adhesive (see paragraph 0026, 0030) for securing around the portions of the foot (0030). At the time the invention was made, it would have been obvious to one having ordinary skill in art to use the teaching of having straps and adhesive on the straps to the device of Burgess, as taught by Turtzo to better secure the device to foot of the user.

Response to Arguments

17. Applicant's arguments filed 1/22/08 have been fully considered but they are not persuasive. With respect to applicant's note that the draft amendment has been published in "Public Pair" and request for the draft amendment to be removed from "Public Pair" this has been reviewed. The draft amendment has been removed from "Public Pair".

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18. With respect to applicants assertion that the amendment limitations are supported in originally filed specification, to that the examiner respectfully disagrees. The originally filed specification does not support having definitive disclosure of structure or property that results in the strength of the “sufficiently stretch-resistance” and “sufficient adhesive strength” limitations of claims, wherein the “sufficient” aspect of the claim. In originally filed specification in paragraphs 0018, 0059 and 0069 the specification sets forth the material used to make the applicant's claimed invention and paragraphs 0028, 0029, 0031 and 0040 discloses adhesive and use of adhesive. However, all of these paragraphs and the remainder of the specification fails to discloses the property of the adhesive strength with any specific specificity. Thus, it cannot be discerned what “sufficiently” stretch-resistant and adhesive strength explicitly or specifically defines in such a way to overcome the rejection under 35 USC 112.

Applicant also argues that the Burgess device does not discloses an orthotic foot support device, to that the examiner respectfully disagrees. Applicant's claims recitation of limitations orthotic comprising a foot support device having a thin flexible stretch-resistance sole member with a sole extending under the foot, sufficiently stretch-resistance to restrict extension and stretching having sufficient adhesive strength to maintain the sole and to restrict extension and stretching does not provide any distinct or definite structure and/or property of a material of the claimed structures that would result in stretch-resistant insole different from the that support of Burgess's device. In response to applicant's arguments, the recitation of an “orthotic foot support device” has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural

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limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

19. Further, Burgess as discussed above, meets the claimed limitations, since a reasonably broad interpretation by the examiner of applicant's claimed invention is met by the invention disclosed by Burgess. Burgess discloses a foot protection device having a thin flexible sole support member having sufficient stretch resistance comprising adhesive having sufficient strength when adhere to bottom of foot inherently would prevent extension and stretching of outer skin of the sole of the foot and result into restricting plantar fascia.

20. Applicant further argues that the Burgess does not discloses the sole member excluding the portion of the foot under the four small toes, to that the examiner respectfully disagrees. Burgess's device discloses that the device with the ability to be "cut to fit" by the wearer prior to use in column 4 lines 61-63 inherently discloses to provide the device to cover foot to exclude the portion of foot under the four small toes.

21. With respect to applicant's argument's that Burgess does not teach sole member which is sufficiently stretch-resistance to restrict extension and stretching of the outer skin tissue on the sole of the foot, when adhered to, not Burgess teach "an adhesive layer of sufficient adhesive strength to maintain said stretch-resistance sole member in place on the outer skin tissue on the sole of the foot", "to restrict stretching of the outer skin tissue" or "to restrict stretching of the plantar fascia", to that the examiner respectfully disagrees. Applicant's claims recitation of limitations orthotic comprising a foot support device having a thin flexible stretch-resistance sole member with a sole extending under the foot, sufficiently stretch-resistance to restrict extension and stretching having sufficient adhesive strength to maintain the sole and to restrict extension and stretching does not provide any distinct definite structure and property that would result in stretch-resistant insole different from the that support of Burgess's device.

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Further, Burgess as disclosed above meets the claimed limitations, since, as broadly interpreted by the examiner the claimed limitations of applicant's claimed invention would read on the Burgess device having thin flexible sole support member having sufficient stretch resistance comprising adhesive having sufficient strength when adhere to bottom of foot inherently would prevent extension and stretching of outer skin of the sole of the foot and result into restricting plantar fascia. Further, The originally filed specification does not support having definitive disclosure of structure or property that results in the strength of the "sufficiently stretch-resistance" and "sufficient adhesive strength" limitations of claims, wherein the "sufficient" aspect of the claim.

22. With respect to applicant's argument to thickness of the device, please see rejection above.

23. With respect to applicant's argument regard to the Turtzo in view of Burgess, the examiner withdrew the rejection. As noted above, the examiner merely used the teaching straps of Turtzo to use straps to the device of Burgess to have orthotic to support the foot of the user as disclosed in the rejection above.

Conclusion

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Green (2003/0145495) discloses a flexible orthotic device. Stephenson (2005/0011084) discloses a disposable slipper. Kawata (2004/0261294) discloses a shoe insole. Spence (3,449,844) discloses a protective inner sole. Innis (1,980,621) discloses a sanitary sandal.

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25. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TARLA R. PATEL whose telephone number is (571)272-3143. The examiner can normally be reached on M-T 6-3.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TP

/Tarla R Patel/

Examiner, Art Unit 3772

/Patricia Bianco/

Supervisory Patent Examiner, Art Unit 3772